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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,295	03/22/2004	Paulo LaColla	11874-076-999	1837
20583	7590	10/18/2007		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EXAMINER WILLIAMS, LEONARD M	
			ART UNIT	PAPER NUMBER
			1617	
			MAIL DATE	DELIVERY MODE
			10/18/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/806,295

Applicant(s)

LACOLLA ET AL.

Examiner

Leonard M. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 19-24, 27-46 and 49-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 57-65 is/are allowed.
- 6) ☒ Claim(s) 19-24, 27-46 and 49-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

Detailed Action

**State of Claims**

No claims have been amended in the present response received 07/20/2007.

Claims 19-24, 27-46 and 49-64 are currently pending.

Claims 1-7, 10-11, 14-18 and 47-48 are cancelled.

Claims 8-9, 12-13 and 25-26 are withdrawn.

**Response to Arguments**

Applicant's arguments filed 07/20/2007 have been fully considered but they are not persuasive. The applicant's have argued that the use of *In re Heinze* in order to help address the substitution pattern of applicant's claimed formula at R4', R6', and R7' (and R5'), in the rejection, has been incorrectly relied upon for support. The examiner appreciates the applicant's pointing out the perceived deficiencies of *In re Heinze* in this matter. The examiner respectfully points the applicants to the body of the rejection (bottom of pages 4 to top of page 5) where the examiner sets forth the description of Williams et al's HIV reverse transcriptase inhibitors (see col. 1 line 15 to col. 15 line 23). Specifically formula A of Williams et al. disclosed, in col. 1 line 50 to col. 8 line 15, teaches that X can be -H, -Cl, -F, -Br (etc...); Y can be -S(O)<sub>n</sub>- where n can be 0, 1 or 2 (col. 2 lines 27-33); R can be an aryl group either unsubstituted or substituted with one or more differing groups (col. 2 line 45-55); Z can be -C=W-NR<sub>2</sub>R<sub>3</sub> (wherein W

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can be O and R2 and R3 can be H; col. 2 line 66 to col. 3 line 10). The substitution pattern(s) Williams et al. describes in formula A (and the possible functional groups contained therein) encompasses the compounds and substitution patterns of formula (I) presently claimed. In support of such, the examiner respectfully points out that formula (I) of claim 1 of the present application is not limited to any substitution pattern and or functional group presentation as claimed. Claim 19 does include alternative embodiments within the claim, specifically on page 3 of the claims: "wherein if R5' is...then at least one of R4', R6' and R7' is not hydrogen; or alternatively, wherein at least two of R4', R5', R6', R7' are not hydrogen;" The examiner points out that the claim language clearly are including these as alternative embodiments that do not limit the rest of the claim as written. As Williams et al.'s formula A includes both the same potential substitution pattern and functional groups as the presently claimed formula (I), and as Williams et al.'s compounds are for use in the treatment of HIV and AIDs they obviate the present claims as written. As the 103(a) rejection is not based solely on the reasoning presented in *in re Heinze*, but on the structural and bioactivity profiles of the compounds of Williams et al., the rejection still holds regardless of whether *in re Heinze* applies.

The examiner does note that as Williams et al. does not exemplify the particular compounds disclosed in claims 57-64 these compounds are deemed free of the art for use in the methods claimed.

The rejections of the previous office action are maintained and reproduced below.

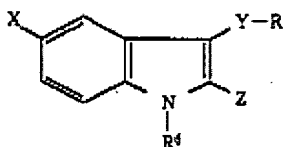
***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-24, 27-46, 49-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (USPN 5527819).

Williams et al. teaches inhibitors of HIV reverse transcriptase for the treatment of HIV infection with the formula:



R is taught to be an aryl with the same substituents as claimed. Y is taught to be S(O)<sub>n</sub> or O, as claimed. Z is selected from various amides, imines, etc., as claimed. R<sup>6</sup> is taught to be selected from, e.g., hydrogen, as claimed. X is taught to be selected from H, Cl, F, BR, etc., as claimed. Treatment of HIV in combination with other anti-HIV agents is also taught. See Abstract; col. 1, line 14-col. 15, line 23. Williams et al. does not teach at least one of R<sup>4'</sup>, R<sup>6'</sup> or R<sup>7'</sup> as a non-hydrogen atom.

It would have been obvious to one of ordinary skill in the art to utilize a compound, as claimed wherein R<sup>4'</sup>, R<sup>6'</sup> or R<sup>7'</sup> is a non-hydrogen because adjacent homologs are considered to be obvious absent unexpected results (*In re Henze*, 85 USPQ 261, 263 CCPA 1950) and members of a homologous series must possess unexpected properties not possessed by the homologous compounds disclosed by the prior art. *In re Hass*, 141 F.2d 127, 60 USPQ 548 CCPA 1944. *In re Hass*, 141 F.2d 127, 60 USPQ 548 (CCPA 1944); *In re Henze*, 85 USPQ 261 (CCPA 1950). In the instant case Applicant has claimed adjacent homologs to those taught in Williams et al. because Applicant's claimed invention encompasses a treatment wherein any one of R<sup>4'</sup>, R<sup>6'</sup> or R<sup>7'</sup> is a methyl group or an halo group. With the teaching of Williams et al., one of ordinary skill in the art would expect to achieve at least similar results in the treatment of an HIV infection with the compounds of the invention disclosed therein when one of hydrogen atoms at the 4, 6 or 7 positions of the indole group are substituted with a methyl or halo group. Furthermore, it is noted that since Williams et al. teaches the treatment of HIV in general, it would have been obvious to one of ordinary skill in the art to treat specific instances of HIV, including those as claimed.

It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to

any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

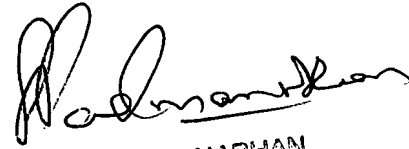
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LMW



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER